

Amendments to the Claims:

This listing of claims will replace all prior versions, and listings, of claims in the application:

Listing of Claims:

1 (Currently Amended). A lipid assembly, being an organized collection of lipids, ~~comprising~~ the lipids consisting of:

(a) ~~a~~ at least one biologically active non-liposome forming lipid having a hydrophobic region and a polar headgroup, wherein the atomic mass ratio between the headgroup and hydrophobic region is less than 0.3, said at least one biologically active non-liposome forming lipid being selected from the group consisting of ceramides, ceramines, sphinganine, sphinganine-1-phosphate, di- or tri-alkylsphingosines and their structural analogs;

(b) a lipopolymer having a hydrophobic lipid region and a hydrophilic polymer headgroup, wherein the atomic mass ratio between the headgroup and hydrophobic region is at least 1.5; and

(c) ~~a~~ at least one liposome forming lipid,

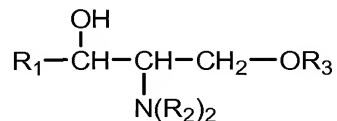
the components of the lipid assembly being selected such that the lipid assembly is chemically and physically stable under storage conditions of 4°C in biological fluids, for at least six months.

2 (Previously Presented). The lipid assembly of Claim 1, wherein the assembly has an additive effective packing parameter in the range of 0.74-1.0.

3 (Previously Presented). The lipid assembly of Claim 1, having a level of water tightly bound to said lipopolymer headgroup of at least 60 molecules of water per lipopolymer headgroup.

4-5 (Cancelled).

6 (Currently Amended). The lipid assembly of Claim 5, wherein said at least one biologically active non-liposome forming lipid has the following general formula (I):



wherein

- R₁ represents a C₂-C₂₆, saturated or unsaturated, branched or unbranched, aliphatic chain, wherein the aliphatic chain may be substituted with one or

more hydroxyl or cycloalkyl groups and may consist of a cycloalkylene moiety;

- R₂, which may be the same or different, represents a hydrogen, a C₁-C₂₆ saturated or unsaturated, branched or unbranched chain selected from the group consisting of an aliphatic chain, an aliphatic carbonyl chain and a cycloalkylene-containing aliphatic chain; wherein the aliphatic chain may be substituted with an aryl, arylalkyl or arylalkenyl group;

- R₃ represents a hydrogen, a methyl, ethyl, ethenyl or a phosphate group.

7 (Previously Presented). The lipid assembly of Claim 6, wherein said biologically active non-liposome forming lipid is a C₂-C₂₆ ceramide.

8 (Currently Amended). The lipid assembly of Claim 6, wherein said at least one biologically active non-liposome forming lipid is N,N-dimethylsphingosine (DMS).

9 (Cancelled).

10 (Previously Presented). The lipid assembly of Claim 1, wherein said lipopolymer comprises a polymer headgroup selected from the group consisting of polyethylene glycol (PEG), polysialic acid, polylactic acid, polyglycolic

acid, apolylactic-polyglycolic acid, polyvinyl alcohol, polyvinylpyrrolidone, polymethoxazoline, polyethyloxazoline, polyhydroxyethyloxazoline, polyhydroxypropyloxazoline, polyaspartamide, polyhydroxypropyl methacrylamide, polymethacrylamide, polydimethylacrylamide, polyvinylmethylether, polyhydroxyethyl acrylate, and derivatized celluloses.

11 (Previously Presented). The lipid assembly of Claim 10, wherein said polymer headgroup is polyethylene glycol (PEG) having an atomic mass in the range of about 750 Da to about 20,000 Da.

12 (Cancelled).

13 (Previously Presented). The lipid assembly of Claim 10, wherein said PEG has an atomic mass of 2,000Da (2kPEG).

14 (Currently Amended). The lipid assembly of Claim 1, wherein said at least one liposome forming lipid is a phospholipid.

15 (Cancelled).

16 (Previously Presented). The lipid assembly of Claim 14, wherein said phospholipid is a glycerophospholipid selected from the group consisting of phosphatidylglycerol (PG), phosphatidylcholine (PC), phosphatidic acid (PA),

phosphatidylinositol (PI), phosphatidylserine (PS),
sphingomyelin (SPM) and derivatives of the same.

17 (Withdrawn/Currently Amended). The lipid
assembly of Claim 1, wherein said at least one liposome
forming lipid comprises a cationic lipid.

18 (Withdrawn). The lipid assembly of Claim 17,
wherein said cationic lipid is a monocationic lipid having a
headgroup selected from the group consisting of 1,2-
dimyristoyl-3-trimethylammonium propane (DMTAP); 1,2-
dioleyloxy-3-(trimethylamino) propane (DOTAP); N-[1-(2,3,-
ditetradecyloxy)propyl]-N,N-dimethyl-N-hydroxyethylammonium
bromide (DMRIE); N-[1-(2,3,-dioleyloxy)propyl]-N,N-dimethyl-
N-hydroxy ethyl-ammonium bromide (DORIE); N-[1-(2,3-
dioleyloxy) propyl]-N,N,N- trimethylammonium chloride
(DOTMA); 3β [N-(N',N'- dimethylaminoethane) carbamoyl]
cholesterol (DC-Chol); and dimethyl-dioctadecylammonium
(DDAB).

19 (Withdrawn). The lipid assembly of Claim 18,
wherein said cationic lipid is a polycationic lipid having a
headgroup selected from the group consisting of spermine and
spermidine.

20 (Withdrawn). The lipid assembly of Claim 19,
wherein said polycationic lipid is N-[2-[[2,5-bis[3-

Appln. No. 10/551,649
Amdt. dated July 12, 2011
Reply to Office action of April 12, 2011

aminopropyl)amino]-1-oxopentyl]amino]ethyl]-N,N-dimethyl-2,3-bis[(1-oxo-9-octadecenyl)oxy]-1-propanaminium (DOSPA) or ceramide carbamoyl spermine (CCS).

21-25 (Cancelled).

26 (Previously Presented). A pharmaceutical composition comprising a physiologically acceptable carrier and an amount of a lipid assembly in accordance with claim 1, which is sufficient to achieve a biological effect at a target site.

Claims 27-80 (Cancelled).

81 (New). A lipid assembly in accordance with claim 1, and further including a non-lipid therapeutically active agent in association therewith.

82 (New). A pharmaceutical composition in accordance with claim 26, and further including a non-lipid therapeutically active molecule, either in association with or separate from said lipid assembly.

83 (New). A lipid assembly in accordance with claim 1, and further including a targeting substance in association therewith.

84 (New). A pharmaceutical composition comprising a physiologically acceptable carrier and an amount of a lipid assembly in accordance with claim 81, which is sufficient to

Appln. No. 10/551,649
Amdt. dated July 12, 2011
Reply to Office action of April 12, 2011

achieve a biological effect at a target site.

85 (New). A pharmaceutical composition comprising a physiologically acceptable carrier and an amount of a lipid assembly in accordance with claim 83, which is sufficient to achieve a biological effect at a target site.